K113711

PULPDENT CORPORATION

MAR - 5 2012

80 Oakland Street
Watertown, MA 02472
USA

TEL: 617-926-6666
FAX: 617-926-6262
Pulpdent@pulpdent.com

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk
80 Oakland Street
Watertown, MA 02472 USA

Telephone: 617-926-6666
Fax: 617-926-6262
Email: ken@pulpdent.com

DEVICE:

Trade Name: ***Lime-Lite II***
Classification Name: Calcium hydroxide cavity liner.
FDA Product Code: 76 EJK, 21 CFR Part 872.3250

PREDICATE DEVICES:

Pulpdent *Limelight*

Scientific Pharmaceuticals *Fluoroseal Dentin Sealer and Cavity Liner*

DESCRIPTION AND INTENDED USE:

Lime-Lite II is a light-cured, calcium and fluoride releasing, radiopaque dental liner/base material that contains hydroxyapatite in a urethane dimethacrylate resin. Lime-Lite II is used to line cavity preparations before restoration.

COMPARISON WITH PREDICATE PRODUCTS:

Lime-Lite II is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

PRODUCT	DESCRIPTION	INTENDED USE	COMPOSITION
Lime-Lite II	Calcium and fluoride releasing, light cured, radiopaque dental liner/base material in a urethane dimethacrylate base.	Line cavity preparations before restoration.	Acrylate resins Hydroxyapatite Calcium hydroxide *and/or* Calcium phosphate tribasic Photo-chemistry Glass filler
Pulpdent Limelight K953079	Calcium and fluoride releasing, light cured, radiopaque dental liner/base material in a urethane dimethacrylate base.	Line cavity preparations before restoration.	Acrylate resins Calcium hydroxide Photo-chemistry Glass filler
Scientific Pharmaceuticals Fluoroseal K860633	Calcium and fluoride releasing, light cured, radiopaque dental liner/base material in a resin base.	Line cavity preparations before restoration	Resin Base Hydroxyapatite Photo-chemistry

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Summary of Performance Testing – Bench

The following test results demonstrate that *Lime-Lite II* performs as intended:

Light Cure Setting Time	< 20 seconds
Working time in ambient light	> 5 minutes
Depth of cure	2 mm
Compressive Strength	238 ± 33 MPa, 34,500 ± 4785 p.s.i.
Flexural Strength	57 ± 10 MPa, 8265 ± 1450 p.s.i.
Density	1.620 g/ml
pH	10 ± 0.5
Water absorption	0.025 mg/mm^3 / 25μg/ mm^3
Shelf-life	Two years

SAFETY AND EFFECTIVENESS:

From the above comparisons, the bench testing and the organizational experience with Lime-Lite, it can be concluded that *Lime-Lite II* is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3250 and CFR 872.3260 and have been used successfully by dental professionals for more than ten years with no reports of adverse events.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kenneth J. Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

MAR - 5 2012

Re: K113711
Trade/Device Name: Lime-Lite™ II
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Codes: EJK
Dated: December 13, 2011
Received: December 21, 2011

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113711

Device Name: ***Pulpdent Lime-Lite™ II***

Indications For Use:

Lime-Lite II is a light-cured, calcium and fluoride releasing, radiopaque dental liner/base material that contains hydroxyapatite in a urethane dimethacrylate resin. *Lime-Lite II* is used to line cavity preparations before restoration.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
vision of Anesthesiology, General Hospital
fection Control, Dental Devices

510(k) Number: K113711